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Summary of Safety and Effectiveness for the InScope Endoscopic Multi-Fire Clip Applier

submitted by

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Identification of a Legally Marketed Predicate Device

The InScope Endoscopic Multi-Fire Clip Applier is substantially equivalent to the legally marketed Olympus HX-5/6-1 Endoscopic Clipping Device manufactured and marketed by the Olympus Optical Company, Ltd pursuant to 510(k) K963160.

Device Description

The InScope Endoscopic Multi-Fire Clip Applier is designed for gastrointestinal endoscopic clipping for marking and hemostasis. It consists of a control handle, an insertion tube, jaws at the distal end for gripping the tissue, and up to 5 clips that can be attached to the tissue individually with each actuation of the device handle. The device is provided sterile and is for one time use only.

Intended Use

The Endoscopic Multi-fire Clip Applier was designed to be used with an endoscope to place clips in the gastrointestinal (GI) tract for the purpose of endoscopic marking, hemostasis of mucosal and submucosal defects < 3 cm, bleeding ulcers, arteries < 2 mm, polyps < 1.5 cm in diameter, and anchoring to affix jejunal feeding tubes to the wall of the small bowel. The device is not intended for repair of gastrointestinal tract lumenal perforations.

Summary of Technological Characteristics

Technological characteristics of the InScope Endoscopic Multi-Fire Clip Applier were compared with the Olympus HX-5/6-1 Endoscopic Clipping Device manufactured and

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marketed by the Olympus Optical Company, Ltd pursuant to 510(k) K963160. It was determined that the compared devices are technologically similar.

Summary of Performance Data

The InScope Endoscopic Multi-Fire Clip Applier complies with the following standards, practices, and guidances:

- Sterilization of health care products—Radiation sterilization—Substantiation of 25 kGy for radiation sterilization as a sterilization Does, *AAMI TIR 27* – Method VDmax: 1996, Approved 9 May 1996
- Sterilization of health care products— Requirements for validation and routine control—Radiation sterilization, *ANSI/AAMI/ISO 11137—1994*, Approved 25 May 1994 by Association for the Advancement of Medical Instrumentation, Approved 11 July 1994 by American National Standards Institute, Inc.
- *ISO 10993-7,* Biological Evaluation of Medical Devices—Part 7: Ethylene oxide. Second Edition 1996-08
- *ISO 10993-1,* Biological evaluation of medical devices—Part 1: Guidance on the selection of tests: *International Standards Organization*
- *ASTM F67-00,* Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700*)*
- *ASTM F136-98,* Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications:
- *ASTM F138-97*, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants
- *ASTM F899-95*, Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments
- *ASTM F3063-00*, Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants

The InScope Endoscopic Multi-Fire Clip Applier is substantially equivalent to the legally marketed Olympus HX-5/6-1 Endoscopic Clipping Device manufactured and marketed by the Olympus Optical Company, Ltd pursuant to 510(k) K963160. This has been demonstrated through bench testing and comparative analysis of features. Bench tests included

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scope passage, rotation, clip deliverability, vessel sealing, and minimum and average clip removal force.

The tissue contact materials used to fabricate the InScope Endoscopic Multi-Fire Clip Appliers have a long history of safe usage in medical devices. Since the InScope Endoscopic Multi-Fire Clip Applier meets the requirements of the stated standards and embodies technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The InScope Endoscopic Multi-Fire Clip Applier will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 7 2002

Mr. Bruce Weber
Vice President, Product Assurance
Syntheon, LLC
8210 NW 27th Street
MIAMI FL 33122

Re: K013889
Trade/Device Name: Endoscopic Multi-Fire Clip Applier
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: 78 FHN, MND
Dated: November 21, 2001
Received: November 23, 2001

Dear Mr. Weber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

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510(k) Number (if known): K013889

Device Name: InScope Endoscopic Multi-Fire Clip Applier

Indications for Use:

The Endoscopic Multi-fire Clip Applier was designed to be used with an endoscope to place clips in the gastrointestinal (GI) tract for the purpose of endoscopic marking, hemostasis of mucosal and submucosal defects < 3 cm, bleeding ulcers, arteries < 2 mm, polyps < 1.5 cm in diameter, and anchoring to affix jejunal feeding tubes to the wall of the small bowel. The device is not intended for repair of gastrointestinal tract lumenal perforations.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013889